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EXAMINER	
HENLEY III,R	

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 1/26/90 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-27 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-27 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

Claims 1-27 are presented for examination.

The disclosure statement filed January 26, 1990 has been received and the papers thereof considered as reflected by the PTO form-1449 which is attached to this action.

Claims 9, 10, 14, 16, 18, 21, 22 and 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In further explanation:

(1) In claim 10, it cannot be determined if the mixture of inorganic and organic lactic acid salts required therein to be a further required component of the claim 1 composition are exclusive to those which are already required to be present in claim 1;

(2) In claims 9 and 22, it is provided for that "N" may equal 1. However, when such is the case, the compound would then appear to be no more than a single salt which is inconsistent with the term "polymer" used to qualify the type of structure in the claim;

(3) In claims 14, 16, 21 and 27, the term "organic lactic acid salt" is redundant insofar as lactic acid is itself organic;

(4) In claim 18, it appears that the salt would correctly comprise L(+)-lactate anion and at least one cation selected from the designated amino acid rather than two intact acid components.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-4, 10-12, 14, 15, 17, 23 and 24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kober.

Note particularly the following:

(1) Column 2, lines 62-68, 78-82 and 92-99 where organic and/or inorganic lactates are taught and sodium lactate is highlighted;

(2) Column 5, lines 1-5 where the teaching of fruit juice is seen to meet the claim requirements respecting carbohydrates such as fructose. The functional language such as at lines 6-9 of instant claim 1 and that employed throughout the composition claims has been noted, but as is well established, the mere recitation of a newly discovered function or property, inherently possessed by a composition of the prior art, does not cause claims drawn thereto to distinguish over that prior art. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

The rejection of the method claims is proper since the recited intent is to "supply nutritional supplementation to mammals"; a requirement clearly met by Kober.

Claims 1-7, 10-20 and 23-27 are rejected under 35 U.S.C. § 103 as being unpatentable over Millman in view of Kober.

Millman teaches an oral composition for supplying nutrition to a host in need thereof which comprises free amino acids or salts thereof, carbohydrates of the type claimed as well as electrolytic salts such as those of potassium, calcium, sodium and magnesium. Note, for example, column 7, lines 23-44 and column 8 lines 32-58.

The differences between the above and applicant's claimed subject matter lie in that one or more lactate salts of the compounds are not highlighted as useful and applicant's specified proportioning of ingredients is not highlighted.

However, to the skilled artisan, it would have been obvious to reconcile these differences and said artisan would have been motivated to do so in view of Kober who teaches that in aqueous, orally administrable nutrient compositions which contain calcium, magnesium, phosphorus and other mineral elements, physiologically acceptable organic/inorganic base-lactate acid salts may be employed so as to prevent instability. Note column 2, lines 62-99. Recognizing this, the skilled artisan would have been motivated to use at least one lactate salt for those salts of Millman by a reasonable expectation of successfully improving the stability of the composition.

The optimum proportioning of ingredients in such a composition is a matter ordinarily determined by persons of ordinary skill in the art.

Claims 1-27 are rejected under 35 U.S.C. § 103 as being unpatentable over Adibi et al. in view of Kawajiri.

Adibi et al. teach an orally administrable, aqueous nutrient composition which may comprise certain amino acid oligopeptides, (not effectively excluded from applicant's claims), free amino acids, oligosaccharides and electrolytes (note page 3, line 9 - page 6, line 18).

The differences between the subject matter disclosed by Adibi et al. and that claimed by applicant lie in (1) organic/inorganic base-lactic acid salts of the type specified by

applicant are not highlighted; and (2) applicant's claim specified proportioning of ingredients is not, per se, taught. Applicant's use of functional language as exemplified in claims 1 and 14 for indicating the amounts of the composition to be administered (i.e. claim 1) as well as the intended purpose for which the claimed compositions are to be used has been noted by the Examiner. However, as discussed in the above rejection over Kober, such language absent objective evidence to the contrary, is not seen to distinguish over the prior art and thus is not seen to be a difference to be reconciled under 35 USC 103.

To reconcile those differences identified above, however, would have been obvious to the skilled artisan and said artisan would have been motivated to do so in view of Kawajiri. This patentee teaches that in aqueous amino acid-electrolyte-sugar solutions, not seen to be physically or structurally distinguishable from the oral preparations of Adibi et al., instability is encountered and provides for the use of lactate salts of the type claimed by applicant as a means for stabilizing such preparations. Note column 1, lines 49-57 and claim 1, lines 7-9. Recognizing this, one of ordinary skill in the art would have been motivated to employ lactate salts when administering a nutrient composition of the type claimed by applicant to a host encompassed by applicant's claims, especially since Adibi clearly prefers that free amino acids be supplied in a storage stable

form. While not highlighted in the art, applicant's claim designated amino acid-lactate salts are deemed to be obvious extensions of the prior art and their selection to be within the purview of one of ordinary skill in the art. Similarly, the optimum proportioning of ingredients is considered to be a matter routinely determined by persons skilled in this art.

From the above, the claims are deemed to encompass no more than prima facie obvious subject matter and accordingly are properly rejected under 35 USC 103. None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Ray Henley whose telephone number is (703) 308-3531.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Frederick E. Waddell
Supervisory Patent Examiner
Group 120

RH

HENLEY:nmb
July 30, 1991
July 24, 1991